

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Ilan et al

Serial No. 10/675,045

Group Art Unit: Not yet determined

Filed: September 30, 2003

Examiner: Not yet determined

Title: GLUCOCEREBROSIDE TREATMENT OF DISEASE

TRANSMITTAL  
INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

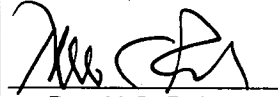
Sir:

Transmitted herewith is an Information Disclosure Statement which is being filed in accordance with 37 C.F.R. §§ 1.56 and 1.97-1.98. The items listed on Form PTO-1449, a copy of which is enclosed, may be deemed to be pertinent to the above-identified application and are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

**EXPRESS MAIL CERTIFICATE**

"Express Mail" Label No.: EL402074112US  
Deposit Date: December 29, 2003

I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.110 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

  
Ronald C. Fedus  
Reg. Exhibit 32,567

DEC 29 2003  
Date

01/05/2004 55ANDAKH 00000016 051135 10675045

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Enz-64(CIP)

1. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:
2. ☐ For each of the following items listed on the enclosed copy of form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.
3. ☐ Any copy of the items on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in the prior ☐ Divisional or ☐ Continuation-In-Part application under 37 C.F.R. §1.60, U.S. Serial No. \_\_\_\_\_, filed \_\_\_\_\_.
4. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:
  - ☐ 37 C.F.R. §1.97(b)(1), within three months of the filing date of the above-identified application.
  - ☐ 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application.
  - ☐ 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office action on the merits.
5. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below.
6. ☒ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):
  - ☐ A check in the amount of \$180.00 is enclosed in payment of the fee.

Enz-64(CIP)

☒ Charge the fee to Deposit Account No. 05-1135, Order No. **Enz-64(CIP)**. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

7. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by:
- a. one of the certification pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and
  - b. the attached petition requesting consideration of this Information Disclosure Statement; and
  - c. the fee due under 37 C.F.R. §1.17(i)(1) which is paid as set forth in paragraph 10 below.
8. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with:
- a. ☐ 37 C.F.R. §1.313(b)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue;
  - b. ☐ 37 C.F.R. §1.313(b)(5), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To Withdraw Application From Issue.
  - c. ☐ The fee due under 37 C.F.R. §1.17(i)(1) is paid as set forth in paragraph 10 below.
9. ☐ I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- ☐ I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

**Enz-64(CIP)**

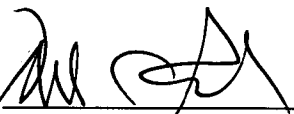
10. ☐ A check in the amount of \$180.00 is enclosed in payment of the fee due under 37 C.F.R. §1.17(i)(1).

☒ Charge the fee under 37 C.F.R. §1.17(i)(1) to Deposit Account No. 05-1135. Order No. **Enz-64(CIP)**. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

☒ The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 05-1135. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

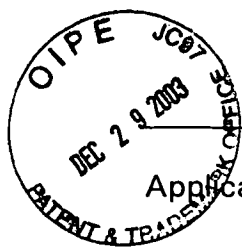
Dated: December 29, 2003

By:   
Ronald C. Fedus  
Registration No. 32,567

Mailing Address:

ENZO LIFE SCIENCES, INC.  
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292 Madison Avenue, 9<sup>th</sup> Floor  
New York, New York 10022  
Telephone: (212) 583-0100  
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**Enz-64(CIP)**



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Ilan et al

Serial No. 10/675,045

Filed: September 30, 2003

Title: GLUCOCEREBROSIDE TREATMENT  
OF DISEASE

Group Art Unit: Not yet determined

Examiner: Not yet determined

527 Madison Avenue, 9<sup>th</sup> Floor  
New York, New York 10022  
December 29, 2003

**FILED VIA EXPRESS MAIL**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §§1.56 & 1.971.98**

Dear Sirs:

Pursuant to the provisions of 37 C.F.R. §§1.971.98, and in full compliance with their duty of disclosure under 37 C.F.R. §1.56, Applicants, through their attorney, are bringing the following twelve (12) documents to the attention of the U.S. Patent and Trademark Office and the Examiner handling their above-identified application:

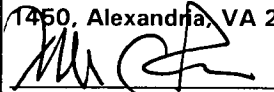
Ilan et al  
Serial No.: 10/675,980  
Filed: September 30, 2003  
Page 2 [Information Disclosure Statement  
– December 29, 2003]

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Ronald C. Fedus  
Reg. Exhibit 32,567

DEC 29 2003

Date

1. Bleicher, P.A., et al., "Expression of murine CD1 on gastrointestinal epithelium," Science 250:679-682 (1990) [Exhibit 1];
2. Collins, C., et al., "RAG1, RAG2 and pre-T cell receptor alpha chain expression by adult human hepatic T cells: evidence for extrathymic T cell maturation," Eur. J. Immunol. 26:3114-3118 (1996) [Exhibit 2];
3. Ilan, et al., U.S. Patent Application No. 10/451,811, filed June 25, 2003, published in International Patent Application No. WO 25/051986, filed December 24, 2001 [Exhibit 3];
4. Ilan, et al., U.S. Patent Application No. 10/375,906, filed February 27, 2003 [Exhibit 4];
5. Madsen, K.L., et al., "Interleukin 10 prevents cytokine-induced disruption of T84 barrier integrity and limits chloride secretion," Gastroenterology 113:151-159 (1997) [Exhibit 5];
6. Mitchell, D.G., et al., "Fatty liver. Chemical shift phase-difference and suppression magnetic resonance imaging techniques in animals, phantoms, and humans," Invest. Radiol. 26:1041-1052 (1991) [Exhibit 6];
7. Namimoto, T., et al., "Adrenal Masses: Quantification of Fat Content with Double-Echo Chemical Shift In-Phase and Opposed-Phase FLASH MR Images for Differentiation of Adrenal Adenomas," Radiology 218:642-646 (2001) [Exhibit 7];
8. Roy-Chowdhury, et al, U.S. Patent Application Serial No. 08/808,629 filed February 28, 1997, specification almost present in divisional applications U.S. Patent Application Serial No. 10/377,628 filed on March 4, 2003, U.S. Patent Application Serial No. 10/377,603 filed on March 4, 2003, and U.S. Patent Application Serial No. 09/447,704 filed on February 28, 1997 [Exhibit 8];
9. Roy-Chowdhury, et al, U.S. Patent Application Serial No. 09/356,294, filed July 16, 1999 and U.S. Patent Application Serial No. 10/385,440 filed on May 9, 2001, specifications of both published on September 11, 2003 as U.S. Patent Application No. 2003-0170258 [Exhibit 9];
10. Sullards, M.C., et al., "Structure determination of soybean and wheat glucosylceramides by tandem mass spectrometry," J. Mass Spectrometry 35:347-353 (2000) [Exhibit 10];

11. Trop, S., et al., "Liver-Associated Lymphocytes Expressing NK1.1 Are Essential for Oral Immune Tolerance Induction in a Murine Model," Hepatology 29:746-755 (1999) [Exhibit 11];
12. Vicari, A.P., et al., "Mouse NK1.1 + T cells: a new family of T cells," Immunology Today 17(2):71 (1996) [Exhibit 12];

The twelve (12) foregoing references (numbers 1-12) were cited in the specification of the instant application.

A completed Form PTO-1449 listing the 12 above-submitted documents is also attached hereto as Exhibit 13.

By this voluntary citation of art, Applicants and their attorney are requesting that the documents be made of record in the present application.

The above citation of documents is not a representation that these documents constitute a complete or exhaustive listing, nor that the above listing necessarily includes the closest or most relevant documents, nor are these documents necessarily a complete listing of all documents known to Applicants or their attorney. It is simply a voluntary citation of documents made in good faith, which is not intended to serve in any way as a substitute for the Examiner's own search.

In view of the general and specific features described and claimed in the present application, Applicants respectfully submit that the present invention is neither disclosed nor suggested by the documents referred to above and is thus patentably distinct thereover. Furthermore, Applicants do not believe, and do not submit, by the citation of these references, that these documents, either by themselves or in combination with other documents, render the invention *prima facie* obvious under the duty of disclosure rules.

Applicants respectfully request that the Examiner make the above-submitted documents of record in the instant application. Applicants further request that the

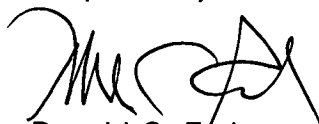


Ilan et al  
Serial No.: 10/675,980  
Filed: September 30, 2003  
Page 5 [Information Disclosure Statement  
– December 29, 2003]

Examiner consider these documents as any of them may relate to the instant application.

The fee under 37 C.F.R. §1.17(p) for filing this Information Disclosure Statement is \$180.00. The Patent and Trademark Office is hereby authorized to charge the amount of this fee (and any other fees in connection with this IDS) to Deposit Account No. 05-1135, or to credit any overpayment thereto.

Respectfully submitted,



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Natalie Bogdanos  
Registration No. 51,480  
Attorneys for Applicants

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Enz-64(CIP)

Form PTO-1449 U.S. Department of Commerce (REV. 8-83) Patent and Trademark Office INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)	Atty. Docket No. ENZ-64(CIP)	Serial No. 10/675,980
	Applicants: Ilan, et al	
	Filed: Sep. 30, 2003	Group: Not yet known

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPRO- PRIATE
	10 3 7 5 9 0 6		Ilan et al			3/4/03
	08 8 0 8 6 2 9		Roy-Chowdhury, et al			2/28/97
	0 1 7 0 2 5 8	2003	Roy-Chowdhury, et al	A1		

## FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	TRAN- SLATION YES NO
WO 25 0 5 1 9 8 6	12/24/01	Ilan et al			

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Bleicher, P.A., et al., "Expression of murine CD1 on gastrointestinal epithelium," <u>Science</u> 250:679-682 (1990)
	Collins, C., et al., "RAG1, RAG2 and pre-T cell receptor alpha chain expression by adult human hepatic T cells: evidence for extrathymic T cell maturation," <u>Eur. J. Immunol.</u> 26:3114-3118 (1996)
	Madsen, K.L., et al., "Interleukin 10 prevents cytokine-induced disruption of T84 barrier integrity and limits chloride secretion," <u>Gastroenterology</u> 113:151-159 (1997)
	Mitchell, D.G., et al., "Fatty liver. Chemical shift phase-difference and suppression magnetic resonance imaging techniques in animals, phantoms, and humans," <u>Invest. Radiol.</u> 26:1041-1052 (1991)
	Lachman, et al, "Massive hepatic fibrosis in Gaucher's disease: clinico-pathological and radiological features," <u>Q. J. Med</u> 93:237-244 (2000)

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce

(REV. 8-83) Patent and Trademark Office

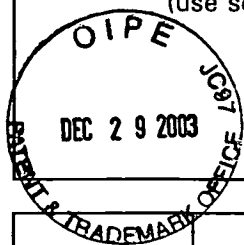
INFORMATION DISCLOSURE CITATION  
(use several sheets if necessary)Atty. Docket No.  
ENZ-64(CIP)

Serial No. 10/675,980

Applicants: Ilan, et al

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Group: Not yet known



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EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPRO- PRIATE

## FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	TRAN- SLATION YES NO

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Namimoto, T., et al., "Adrenal Masses: Quantification of Fat Content with Double-Echo Chemical Shift In-Phase and Opposed-Phase FLASH MR Images for Differentiation of Adrenal Adenomas," <u>Radiology</u> 218:642-646 (2001)
	Sullards, M.C., et al., "Structure determination of soybean and wheat glucosylceramides by tandem mass spectrometry," <u>J. Mass Spectrometry</u> 35:347-353 (2000)
	Trop, S., et al., "Liver-Associated Lymphocytes Expressing NK1.1 Are Essential for Oral Immune Tolerance Induction in a Murine Model," <u>Hepatology</u> 29:746-755 (1999)
	Vicari, A.P., et al., "Mouse NK1.1 + T cells: a new family of T cells," <u>Immunology Today</u> 17(2):71 (1996)

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